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SECRETARY'S ADVISORY COMMITTEE ON
HERITABLE DISORDERS IN NEWBORNS AND CHILDREN

Friday, January 27, 2012

Afternoon Session

1:15 p.m.-2:30 p.m.

Park Hyatt Hotel
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1 CHAIRMAN BOCCHINI: All right. Let's go
2 ahead and call the meeting to order. I know we
3 have a couple of more members who are probably
4 returning, but I believe we have a quorum. And we
5 do have a lot of business in this session. And we
6 do want to finish on time so that people could get
7 to their airplanes.

8 So we're going to start with Nancy Green
9 giving a report on Implementing Point-of-Care
10 Newborn Screening, tab seven in your agenda book.
11 And this may require a vote for product support; is
12 that correct? Okay.

13 DR. GREEN: Thank you, Dr. Bocchini, for
14 allowing me to give this report. And I think I
15 don't have to say the obvious, which is I think
16 this is a timely report given the focus of the
17 various foci of this meeting. So thank you very
18 much.

19 And I look forward to the discussion
20 following my presentation and expect that Coleen
21 and Jeff, as current or former co-chairs and
22 involved with this process, as well as Alex Kemper

1 and others around the table, who have been active
2 writers, co-writers, that you'll be involved with
3 the discussion as well.

4 So it was just about a year ago to the
5 January meeting of 2011 that we first started
6 talking about pulling together the thoughts on
7 point-of-care newborn screening. And I would like
8 to point out that the gestational period for a
9 horse is 11 months and for a camel is 12. So, just
10 FYI.

11 [Laughter.]

12 DR. GREEN: Okay. So I'm going to
13 summarize the manuscript that's in your reading
14 materials. I think what you have is probably
15 accurately described as a penultimate draft.
16 Identify any remaining issues for the manuscript.
17 And in fact, some things that have arisen from
18 today's discussion I'd like to add. And then
19 solicit input, support, as appropriate from this
20 committee.

21 So, for the sake of time, I'm going to go
22 through the slides very fast, but please interrupt

1 me if you'd like a clarification or we can get back
2 to it.

3 So, the point-of-care testing itself has
4 previously been defined as testing, or in this
5 case, it would be screening at the point of -- site
6 of patient care, with the driving notion being that
7 the test and of course the results would be a
8 convenience and immediacy to the results. And that
9 would improve the likelihood of receiving results
10 and making timely medical decisions.

11 And obviously this centralized laboratory
12 would not constitute point-of-care screening.

13 So the context of the manuscript I think
14 is, as I said, is obvious, and the juxtaposition
15 between public health and pediatric care about
16 newborns also involved issues regarding how
17 decisions are made, the evidence review that we do
18 and then some of the others that came up earlier,
19 particularly the task force. And then the triple
20 Rs, the roles, responsibility and resources. And I
21 think actually Coleen, when you discussed the
22 report this morning of the Subcommittee on Follow-

1 up and Treatment, that the CCHD presentation from
2 Maryland was -- exemplified many of the issues
3 around those triple Rs. And in fact, the
4 manuscript as I hope you've seen, is far from
5 prescriptive. It really is to outline the issues
6 and that with the understanding that many of the
7 distribution of those roles, responsibilities,
8 resources will likely vary by condition.

9 And so I'd just like to list the
10 coauthors. If anybody here feels that they are not
11 on the list and feel that they ought to be, we're
12 happy to -- we've already sort of exceeded the six
13 author limit, so we'd be happy to include you and
14 right -- but I would like to acknowledge the
15 contributions of many wise people.

16 So again, this is a framework for
17 evaluation, defining what point-of-care screening
18 really is and whether then helping provide some
19 background as far as making decisions about whether
20 point-of-care screening tests could be added to the
21 panel. And but I'd say the slant of the manuscript
22 is really, we tried to take the public health

1 perspective, but also incorporate issues around
2 providers, nursery, procedures, and the like, and
3 the public.

4 So the manuscript is organized, as you
5 can see, the definitions, and the potential of
6 decentralized screening in terms of immediacy of
7 results. And that may be beyond the context of
8 this meeting, this discussion. But I would like to
9 sort of raise the question that point-of-care
10 screening, for some disorders where immediate
11 results and action are needed may lead to some
12 consideration eventually, depending upon a myriad
13 of issues including incapacity, around the current
14 panel, you know, galactosemia or something like
15 that. But again, that's not for today's
16 discussion.

17 So what are the characteristics of
18 newborn screening? I don't have to talk to this
19 group about -- and the point being, this is
20 essential public health activity. And I think,
21 again, this concept was described very well in the
22 discussion on hyperbilirubinemia screening, to

1 ensure uniform quality and evidence-based
2 recommendations.

3 So what would be then -- what we're
4 proposing as the inclusion criteria for point-of-
5 care screening would be all of the usual important
6 aspects, of course, newborn screening, and then
7 additional criteria. And that would be the urgency
8 of recognition and treatment beyond what would be
9 feasible for centralized laboratory and/or that the
10 screening would be physiologic based. Of course,
11 TcB or pulse oximetry exemplify that.

12 And so really, again, as the discussion,
13 I think, this morning really brought to light that
14 the issue is, in deciding whether something should
15 be -- a condition should be part of clinical care
16 or within the recommended uniform panel, if there
17 are better outcomes, if it's performed under public
18 health mandate. And I think that that's a guiding
19 principle.

20 And then the other aspects being
21 standardization of the technology; feasibility for
22 the decentralized implementation, which I think

1 makes everybody nervous because we haven't done
2 that yet and it's just happening now with CCHD;
3 that screening is feasible in nursery given how
4 orderly nurseries are; and assure, of course, that
5 follow-up diagnosis and care can be provided in a
6 timely and appropriate fashion.

7 So as I mentioned earlier, there's not a
8 single prescription for point-of-care screening.
9 It depends on the condition and then also, other
10 factors, including potentially state legislation.
11 And then other aspects that are relevant to public
12 health that are familiar to public health. And
13 those would be risk of missed cases, the complexity
14 of the screening paradigms. One can imagine if the
15 screening would require an MRI under anesthesia.
16 That's obviously a ridiculous extreme, but that
17 would not be something feasible for point-of-care
18 screening.

19 The extent to which the screening is
20 already part of standard care and I think that
21 topic has been covered -- exemplified this morning.

22 The challenges of confirmatory diagnosis,

1 and we haven't really talked about that today, but
2 certainly, that's come up with those CCHD.

3 And the potential for variability in
4 screening procedures, the validity of the
5 procedures, actually both screening and diagnosis.
6 And those are obviously quite serious
7 considerations.

8 Okay, so just to try to sort of divide
9 the -- we used to say buckets -- but actually
10 you're saying lanes today, so I'm going to borrow
11 from you, Coleen. To identify the lanes, divided
12 this by public health providers and other entities.

13 So for public health, obviously, the
14 assurance about the quality and feasibility in a
15 statewide manner with the overriding issues of
16 quality, timeliness, and equitable delivery of
17 services; assuring feasibility of statewide
18 surveillance, and actually that's come up with
19 respect to CCHD; the integration of clinical
20 services and tracking into the existing systems for
21 newborn screening; and then to assess the impact on
22 clinical care and, certainly, informing the public.

1 And that's not something that we spent a lot of
2 time with this morning, but I think that's an
3 obvious point that would be noncontroversial.

4 Okay, so for the issues for providers and
5 for nurseries, understanding that they're not the
6 same. And we in the past, we talked about how
7 hospital -- agencies that represent hospitals have
8 not been part of this discussion. And so I just
9 would like to remind us of that.

10 But for providers in the nursery and
11 pediatric providers immediately thereafter involved
12 with the diagnosis and treatment, that there's
13 obviously infrastructure required. As I mentioned,
14 the practicality of doing anything -- doing
15 anything in an already loaded nursery schedule.

16 Costs involved. As we've discussed, the
17 responsibilities of the providers within the
18 nurseries and then the providers who would be
19 involved with diagnosis and service delivery. And
20 I think that's something that actually needs to be
21 identified as an important factor.

22 And then, assessing the impact on routine

1 care.

2 And then, the other issues, certainly
3 around coordination, are not trivial, as I'm sure
4 most of you recognize, that there are many
5 stakeholders around nursery procedures, including,
6 of course, families. As I mentioned, the primary
7 care, the newborn nursery services, hospitals,
8 public health agencies, and payers; and that there
9 really needs to coordination, and collaboration,
10 and leadership, I guess, amongst the variety of
11 entities.

12 And the issues that I mentioned about the
13 coordination and avoiding disparities of poor
14 quality services.

15 So as we understand, birth hospitals
16 would have considerable responsibility, obviously,
17 for providing high-quality, presumably standardized
18 screening equipment. They'd have to employ their
19 current or additional employees to do the
20 screening, to provide standardized techniques for
21 performing the screening, recording the results,
22 and communicating those results, both to the family

1 and to public health to ensure continuous quality.

2 And as I mentioned, the timely reporting.

3 And then the coordination across the diagnosis and
4 therapy.

5 So there are some additional issues just
6 to raise, including the criteria -- I think I don't
7 need to talk about this since we've, I think,
8 covered this very well this morning around
9 hyperbilirubinemia, around criteria for clinical
10 services vs. the recommended uniform panel. The
11 interface between all of the various stakeholders,
12 the assurance of input from professional
13 organizations and families, data capture, caps in
14 funding.

15 And then, a point that actually I'd like
16 to attribute to Jeff, if you don't mind, and that
17 is the acceptability to parents, because as these
18 conditions if they're added -- we don't know --
19 there's no sort of limit to the number -- but
20 they're all being done in front of parents. And so
21 there may be acceptability issues that are new.

22 And there have been studies done looking

1 at acceptability of hearing screening, for example,
2 where the vast majority of parents found that to be
3 acceptable over 90 percent. And these were
4 studies, I think, one performed a large study in
5 2001. But we don't know what subsequent screening
6 would do, and again, when we start talking about
7 multiple different procedures, there may be issues.

8 And again, according to this 2001 report,
9 only seven states -- well, seven states required
10 parental consent for hearing screening. So again,
11 what would that do to the understanding for most
12 states that consensus is not required for newborn
13 screenings?

14 So I think those are actually real
15 issues. So thank you, Jeff, for bringing that up.

16 So in summary, this is a manuscript that
17 hasn't been created, written by the Follow-up and
18 Treatment Subcommittee. And to paraphrase Winston
19 Churchill, "This is the end of the beginning" for
20 point-of-care screening.

21 And some of these issues as we sort of
22 think about and deliberate about both specific

1 conditions and also the sort of the generic concept
2 of point-of-care screenings that there may be some
3 implications for screening beyond the newborn
4 nursery that we should just kind of keep in mind.

5 So we seek the support of the manuscript
6 by the committee. And we've had some discussion
7 about whether this should be a subcommittee report
8 or in fact, if there are any subcommittee reports,
9 whether it should be instead a report from the
10 committee.

11 And then of course we would like to
12 submit this to peer-review publication and identify
13 next steps, which would certainly of course be the
14 existing issues, unfolding issues around CCHD as it
15 expands. And then also to really think about
16 whether we do need to engage additional
17 stakeholders, the hospital associations being just
18 one, probably the nurses in the nursery, and
19 potentially others. So I just raise those as
20 questions.

21 And we thank you.

22 DR. BOCCHINI: All right. Thank you.

1 All right. This is open for discussion.
2 The paper was in the agenda book and available.
3 And so for my view, I think it's a very well-
4 written and comprehensive document. I think as you
5 indicated, it very nicely describes the issues and
6 where we are.

7 So, Coleen?

8 DR. BOYLE: I was going to add one thing.
9 Nancy, maybe if you could leave that last slide up.
10 We really like the pictures of the babies.

11 That one right there. So really what we
12 were considering was that this would be an
13 informational document that we would provide to the
14 Secretary, really for education information. So
15 that was your -- we go back to Sara's list. This
16 would be number two, I guess. Yeah.

17 DR. BOCCHINI: All right. Any questions
18 or comments? Any issues related to moving forward?

19 DR. GUTTMACHER: Can I just ask --

20 DR. BOCCHINI: Yes.

21 DR. GUTTMACHER: -- for clarification?

22 Support of the manuscript by the ACHDNC, supporting

1 what? That we are formally endorsing it? Or we
2 are --

3 DR. COPELAND: You can't endorse it.

4 DR. GUTTMACHER: Exactly. So what is
5 support mean exactly?

6 DR. COPELAND: We think it's a good idea,
7 that it contains -- that we're in agreement with
8 what is said in the manuscript.

9 DR. GUTTMACHER: We're in agreement with
10 what's said?

11 DR. COPELAND: The points, the summaries
12 that were made.

13 DR. GUTTMACHER: The summaries. That's
14 different from -- those of us who are Feds are
15 undoubtedly thinking, do we need to have clearance,
16 for instance, to do this? Obviously, if we were to
17 sign on to a document, we would need clearance.
18 And I'm just trying to tease out whether this
19 raises the level of action needing clearance rather
20 than just, gee, it's a great idea?

21 DR. COPELAND: Beverly's not -- Beverly
22 can't say. The very specific issue is it's not an

1 endorsement, because that has legal implications,
2 and that's why it was not labeled as endorsement.

3 DR. BOYLE: And actually, it actually
4 would say that our usual disclaimer line on it, if
5 you look at the --

6 DR. GREEN: So just to be clear then, I
7 guess what we're talking about is the byline,
8 right, would list all the authors and then it would
9 specifically identify the committee with the --

10 DR. GUTTMACHER: If it's listing the
11 committee members as somehow endorsing it, then I
12 would need to get clearance. Signing onto the
13 document -- just like any article, if I was writing
14 an article that said the sky was blue or anything
15 else.

16 DR. COPELAND: So this reflects the will
17 of the committee. And if the committee votes and
18 says they support this, it'll go forward. If you
19 need to abstain, you can. But it won't
20 specifically identify you, and there will be some
21 kind of disclaimer in there that this is not
22 individual works. This is not individual

1 representation, but this reflects --

2 DR. GUTTMACHER: So it does -- and so the
3 members of the committee by supporting this are not
4 being listed as some kind of semi-authors or
5 whatever.

6 DR. COPELAND: Exactly.

7 DR. BOCCHINI: Which has been the process
8 for other articles that have come from
9 subcommittees here.

10 DR. KUS: Just to clarify, I think it's a
11 document that's out there that kind of frames how
12 you can look at this. We're not putting out any
13 specific recommendations in the document. So
14 that's kind of the way I would view it.

15 DR. BOCCHINI: All right. If there are
16 no other questions or comments, I'll entertain a
17 motion to approve this report.

18 Jeff?

19 DR. BOTKIN: I move to support this
20 report under, is it category 2?

21 DR. MCDONOUGH: Second.

22 DR. BOCCHINI: Stephen seconds that

1 motion. So now we need to know if there will be
2 anybody who will need to abstain?

3 Hearing none, we'll go to the next up --
4 next up, we're going to -- your choice.

5 DR. COPELAND: Yes.

6 So, Cathy Wicklund.

7 MS. WICKLUND: Approve.

8 DR. COPELAND: Fred Lorey?

9 DR. LOREY: Yes.

10 DR. COPELAND: Charlie Homer?

11 [No response.]

12 DR. COPELAND: Don Bailey?

13 DR. BAILEY: Yes.

14 DR. COPELAND: Joe Bocchini?

15 DR. BOCCHINI: Approve.

16 DR. COPELAND: Alexis Thompson?

17 DR. THOMPSON: Approve.

18 DR. COPELAND: Andrea Williams?

19 DR. WILLIAMS: Approve.

20 DR. COPELAND: Agency for Healthcare
21 Research and Quality?

22 DR. DOUGHERTY: Approve.

1 DR. COPELAND: Centers for Disease
2 Control and Prevention?

3 DR. BOYLE: Yes.

4 DR. COPELAND: DR. BOTKIN:

5 DR. BOTKIN: Approve.

6 DR. COPELAND: Peter Matern?

7 DR. MATERN: I approve, too.

8 DR. COPELAND: Steve McDonough?

9 DR. MCDONOUGH: Aye.

10 DR. COPELAND: Okay. Food and Drug
11 Administration, Kellie Kelm?

12 DR. KELM: Approve.

13 DR. COPELAND: Health Resources and
14 Services Administration, Michael Lu?

15 DR. LU: Approve.

16 DR. COPELAND: National Institutes of
17 Health?

18 DR. Guttmacher: Approve.

19 DR. COPELAND: And Charlie Homer, are you
20 on the phone?

21 [No response.]

22 DR. COPELAND: Okay. So the motion

1 passes.

2 DR. BOCCHINI: All right. Thank you all
3 very much. Thank you.

4 DR. GREEN: Oh, thank you very much.

5 DR. BOTKIN: Joe?

6 DR. BOCCHINI: Yes?

7 DR. BOTKIN: Can I raise a topic for
8 conversation about this. And I think the paper
9 does a nice job of sort of articulating what the
10 general framework is, what the potential
11 responsibilities are of different stakeholders, et
12 cetera. I don't think it yet, and I don't think
13 it's right for this determination, but just to
14 raise it for perhaps some discussion here. How do
15 we decide of those point-of-care examinations that
16 are common for babies, which ones might fall within
17 the purview of this committee and which ones might
18 not?

19 And we had a little bit of that
20 conversation with hyperbilirubinemia. And so if
21 the Academy of Pediatrics says we think every baby
22 ought to be screened for hyperbilirubinemia, what's

1 the difference between that sort of recommendation
2 and one that might come to this committee? And are
3 there aspects of the condition or aspects of the
4 funding or politics or whatever that would bring it
5 before this body as opposed to the other
6 professional bodies that make recommendations all
7 the time about what they think the standard of care
8 is?

9 And again, I don't think this paper is
10 ready to make -- to draw that line. But I think at
11 some point, the committee needs to think about that
12 issue.

13 DR. BOCCHINI: It is an important issue.
14 And I think you're right. As time goes on, there
15 will be other things that we'll need to address
16 more formally. I agree.

17 DR. GREEN: Maybe the paper needs to be a
18 little more explicit about that, raising that
19 question.

20 DR. COPELAND: Well, there's also the
21 fact the any consumer can bring or any group can
22 bring forward a condition whether or not they think

1 it should be added to the newborn screening panel.
2 And hopefully that public health impact in that
3 analysis will be robust enough in the condition
4 review that if it goes to the condition review that
5 that will be adequately addressed. And hopefully
6 those will be some options.

7 The other reason that we -- the other
8 reason for cooperating more closely with Community
9 Guide and the U.S. taskforce is that if we can get
10 a process that is closer to theirs, in terms of
11 condition voting, et cetera, there may be a
12 possibility for having some reciprocity between the
13 two groups. And so we do get something that might
14 be more appropriate for the taskforce it may be
15 something that we can develop a mechanism to
16 address.

17 DR. BOCCHINI: All right. Chris?

18 DR. KUS: Nancy brought up the idea about
19 something else in early childhood kind of
20 screening. And I think there's some -- one of the
21 things about this universality is the idea that
22 you're in the hospital and it's right after you're

1 born. When you do screening in clinical care, you
2 have to be in that healthcare system. Some people
3 are not in the healthcare system. And so in terms
4 of finding and doing universal screening, it really
5 brings another issue.

6 So I think that's why CCHD, which is
7 saying kids are in and newborn hearing screens are
8 in the hospital; that's the way you capture them.
9 After that, I think there's a lot of other
10 complications in doing it. An example in states
11 with lead screening mandates, we've got lead-
12 screening mandates but we're never getting it to
13 100 percent, and the way we follow it is to provide
14 feedback to docs about what's happening in that.
15 But it's not -- it's not a captive population in
16 some sense.

17 DR. BOCCHINI: Good point.

18 Okay. Let's move forward with the next
19 presentation on Critical Congenital Heart Disease
20 Implementation. I'm going to reverse the order.
21 Coleen has a plane to catch so we're going to let
22 her go first and talk about the Federal Plan of

1 Action for Critical Congenital Heart Disease.

2 DR. BOYLE: So that was a appended to my
3 morning's presentation. It's Boyle.

4 So I'll get started without the slides.

5 As you know or maybe remember, in September when
6 the Secretary decided to go forward with the screen
7 for -- accept the original proposal that was
8 brought forward by the committee and accepted CCHD
9 as part of the recommended uniform screening panel,
10 she came back with specific charges for the
11 agencies. And I'm presenting the work of the
12 various agencies, presenting for my colleagues, the
13 work of the various agencies and responding to that
14 directive by the Secretary.

15 And if you also remember, when the
16 recommendation went forward to the Secretary, we
17 actually highlighted for each agency as part of
18 that recommendation what the agencies -- the
19 responsibility for the agencies.

20 So it's there. Yeah. Great.

21 If you just place that there. I've got
22 it. I've got it. Good. Great. This is my trying

1 to be efficient last night.

2 So as you remember, NIH was essentially
3 charged with research, both research in terms of
4 actually advancing that technology to identify
5 children with CCHD, as well as research related to
6 looking at outcomes related to care and treatment.

7 There's three bullets here in terms of
8 activities involving two NIH agencies, NHLBI and
9 NICHD. NHLBI is providing guidance relative to --
10 they have a common nomenclature tool for coding and
11 classifying congenital cardiovascular
12 malformations. Some of you may be familiar with
13 this. So this is being made widely available.
14 It's part of their pediatric cardiovascular
15 research network.

16 And if you skip to the third bullet
17 there, they also have a Pediatric Heart Network.
18 This is a nine clinical site. And they're
19 assessing the current practices related to CCHD and
20 whether or not the Pediatric Heart Network could
21 provide the venue for conducting evaluations of
22 screens. So they already have this network.

1 And then, some of you in the states may
2 know which states -- it would behoove you, I guess,
3 to know which states these networks are in. You
4 can link on this Pediatric Heart Network. And that
5 might help facilitate from your perspective some
6 ongoing evaluation as you roll out your state
7 programs.

8 The Health Resources and Services
9 Administration was charged with, appropriately,
10 helping with the implementation with state health
11 departments for screening, as well as the
12 education. And many of you, I think most of you in
13 the room, are aware of the fact that there's FOA
14 out on the street from HRSA to fund six
15 demonstration projects for the implementation of
16 CCHD in the states. Those projects will be funded
17 for 3 years.

18 HRSA has also assisting the Newborn
19 Screening Clearinghouse to work with NHLBI and
20 other stakeholders to have the most accurate
21 education materials on the website. There are
22 materials that are already available, and actually,

1 in prior meetings, we had several of those
2 presenters who have those materials come and
3 discuss those with us.

4 And they're also working within a
5 National Newborn Screening Genetics Resource Center
6 to provide state technical assistance as requested.

7 CDC was charged with the ongoing
8 evaluation and surveillance tracking, looking at
9 cost effectiveness and leveraging electronic health
10 records.

11 So in the first bundle, we surveyed, and
12 we have done this twice now, all of our state
13 programs to see where they are in terms of their
14 capacity. This one was prior to the actual
15 acceptance by the Secretary. And then most
16 recently, we resurveyed states to get a better
17 sense of what's going on there.

18 This week, we just started what we call
19 an Epidemiologic Aid or EpiAid project in New
20 Jersey. This is a fairly intense view of really
21 what's going on, focusing on real mechanics,
22 looking at analyzing the data flow and tracking

1 hospitals and following up on missed screens.

2 So we'll have an evaluation with a 30-day
3 window for those EpiAid projects, so we'll have
4 results that could be shared and will be shared and
5 made available to others.

6 And then we have a webinar in March and
7 April really to provide technical assistance to
8 state birth defects and newborn screening programs.

9 Concurrent with what we're doing in New
10 Jersey, we're starting something new, which is
11 essentially the equivalent of an EpiAid but it's
12 economic aid. So we're trying to assess what the
13 cost to the hospital is, real-time cost to the
14 hospital for implementation of newborn screen.

15 And then, we're also developing a cost-
16 effectiveness model using the experience of three
17 other states within that context. Doing some work
18 in trying to leverage electronic health records.
19 This really predated what we were doing with the
20 Secretary's decision. So we had electronic health
21 record activity, which is interfacing with HHS
22 level activities. But now we're trying to

1 concentrate it much more on congenital heart
2 disease.

3 So that's my Federal update.

4 DR. BOCCHINI: Thank you.

5 Questions or comments?

6 All right. Thank you, Coleen.

7 Appreciate it.

8 Now we have Lori Garg. Dr. Garg is the
9 Medical Director of Special Health and Early
10 Intervention Services, Medical Director of Newborn
11 Screening and Genetic Services for the New Jersey
12 Department of Health and Senior Services.

13 DR. GARG: Thank you very much. I know
14 that we're short on time. So I'm just going to
15 whip through this pretty quickly.

16 I was asked to speak about New Jersey's
17 experience with implementing pulse oximetry
18 screening.

19 I think probably the best place to start
20 is right at the beginning, and for us the beginning
21 was June 02, 2011. That is the date that Governor
22 Christie signed into effect legislation that put

1 New Jersey as the first state to mandate pulse
2 oximetry screening in newborns to detect critical
3 congenital heart disease. On the screen, I have a
4 excerpt of the key portion of our legislation,
5 which reads, "The Commissioner of Health and Senior
6 Services shall require each birthing facility
7 licensed by the Department of Health to perform a
8 pulse oximetry screening a minimum of 24 hours
9 after birth on every newborn in its care."

10 From the date of signing of the
11 legislation, we had 90 days until we needed to
12 enact the legislation, so that put us at August 31.
13 I also just wanted to mention that the legislation
14 was unfunded.

15 [Laughter.]

16 DR. GARG: The first thing that we needed
17 to do really was to decide what the role of the
18 department would be in all of this. And so while
19 the hospitals are mandated to screen every baby,
20 the decision was made that we weren't going to
21 mandate how they should screen. This was a point
22 of care test, pertinent to the discussion that we

1 just had earlier. The thought was that since the
2 babies are in the hospital under the care of
3 medical providers, that the hospitals really needed
4 to be responsible for ensuring follow-up and not
5 the Department of Health.

6 Along the same lines, the decision was
7 made that we would not conduct active follow-up of
8 the abnormal screens in the same way that we do
9 with abnormal biochemical newborn screens.

10 The division of licensing was charged
11 with overseeing the hospital compliance with the
12 legislation. And they are within the Department of
13 Health but a different division from where newborn
14 screening sits, which is over in Family Health
15 Services.

16 Initially newborn health screening was
17 charged with developing the best practice
18 guidelines document, but as we got into this rather
19 quickly, we realized that if we wanted to build an
20 effective screening and surveillance system that we
21 really needed to expand the scope of our
22 involvement really in order to support and guide

1 implementation efforts at the hospital level.

2 So the first thing that we did was we
3 convened a working group, the critical congenital
4 heart disease screening working group. It has been
5 a wonderful group of dedicated individuals. We
6 have cardiologists, neonatologists, pediatricians,
7 nurses, nurse midwives, parent advocates. We have
8 representation from the New Jersey Academy of
9 Pediatrics as well as our New Jersey Hospital
10 Association and our Maternal and Child Health
11 Consortia. And in addition, we have representation
12 from the Department of Health, so we have somebody
13 from newborn screening, somebody from birth defects
14 registry, somebody hearing screen and also from
15 licensing.

16 Initially, our main focus was really to
17 develop a recommended protocol, the concern being
18 that we weren't mandating how the hospitals are
19 screening, so we really wanted to get something out
20 to them before the effective date of the
21 legislation so they could look to that, because the
22 concern was that there was a potential that every

1 hospital would do their own thing, and potentially
2 not use the evidence in developing those protocols.

3 This is a copy of our protocol. I'm just
4 passed out some copies of it. We were very
5 fortunate to be able to get a pre-release of the
6 algorithm that was to be published in Pediatrics
7 from the strategies paper. The algorithm was
8 developed by the expert panel from this advisory
9 committee. So we used that as the foundation for
10 development of our algorithm. Mainly the two
11 differences between the two are that our
12 legislation mandated screening of all babies in the
13 hospitals, so basically this reflects that and
14 includes babies in the protocol.

15 The other difference was, to pass, you
16 needed to have 95 or greater in both extremities,
17 upper and lower. And the reason for that -- and
18 not just in one extremity. And the reason for that
19 really was to just try to increase the sensitivity,
20 though we did realize that it might also increase
21 the false positive rate. We also spent a lot of
22 time trying to simplify the algorithm. We weren't

1 going to have time to do intensive training, so we
2 wanted to try to make it simple and break up the
3 steps as best we could.

4 As far as education and training, we did
5 do two webinars. The first one was at the time we
6 released the webinar -- I'm sorry, the protocol.
7 And that one was really just to provide an overview
8 of CCHD, of pulse oximetry screening, to go over
9 the protocol and to talk with the hospitals about
10 implementation. And that was archived on our
11 website.

12 The second webinar that we did was a
13 couple months later, and that one was more around
14 data collection and reporting.

15 Informally, we have had a lot of frequent
16 communication with the hospitals, a lot of back-
17 and-forth, and a lot of technical assistance that
18 we have been providing. But we really have not had
19 time to do the intensive training efforts that we
20 would have liked, and we have a whole slew of
21 things planned. A lot of it is really dependent on
22 resources.

1 Right now, we are working on developing
2 best practice guidelines document. Members of the
3 working group have agreed to write some of the
4 sections. We're working on developing a parent
5 education brochure.

6 And some of the important things that I
7 would like to do, and we're slowly trying to make
8 headway with it, is to really get into the
9 hospitals to develop a train the trainer model, to
10 get to the nurses who are doing good screening, and
11 also to develop a standardized slide deck to have
12 cardiologists and neonatologist go around to the
13 different hospitals.

14 As far as surveillance, we actually
15 didn't get our data system up and running until
16 probably about 2 months after implementation. We
17 spent a lot of time at the beginning to try to find
18 a way to collect individual level data on the
19 babies, I explored the blood spot card, the
20 immunization registry, our electronic birth
21 certificate that we have. Unfortunately, that
22 would've been ideal, but it's an antiquated system,

1 so there was no way of adding any other fields to
2 the EBC. Fortunately for us, New Jersey is just in
3 the beginning stages of developing a new electronic
4 birth certificate, so hopefully within a year a
5 half or so we will have that up and running and be
6 able to collect individual level data.

7 What we do and what we are doing in the
8 interim is collecting quarterly aggregate data from
9 each of the hospitals. We are requesting the
10 number of births and the number of the screens, and
11 then also there to explain any discrepancy between
12 the two numbers. And then also we are using the
13 birth defects registry to capture information on
14 all failed screens. The hospitals report fail
15 screens, whether it's a true positive or not, and
16 then right now what is happening is that one of the
17 nurses from the birth defect registry is calling
18 the hospitals and following up on those and asking
19 a series of questions that we developed to get the
20 screens resolved, the results of evaluation that is
21 done, prenatal history, and any pre-existing
22 histories done prior to the screen.

1 Fortunate for us, this nurse has been at
2 the department for over 25 years and has really
3 wonderful relations with all the nurses in the
4 different hospitals and has really facilitated the
5 communications. This has been a great learning
6 process for us. Eventually, we will go to an
7 electronic module, but this has been a great way
8 for us to get information to the hospitals and also
9 to get information back to help us refine our data
10 questions.

11 It was mentioned that right now in New
12 Jersey, as we speak, actually, we have an -- going
13 on, and we do hope to get information from that.
14 They are visiting 11 hospitals and doing
15 interviews, so we hope to get information back from
16 that, that will help us further refine these
17 questions.

18 Ultimately, when the new EBC is up and
19 running, we will probably in a year and a half or
20 so be able to collect individual level data through
21 that. And then also we will likely continue
22 collecting the failed screens through the --

1 information on the failed screens through the birth
2 defects registry.

3 So I just wanted to switch gears a little
4 and share with you a little bit of the data that we
5 have so far. The first thing, this is from a
6 survey that I did of the hospitals in early August
7 before we have implemented, just trying to assess
8 the lay of the land. What I wanted to share with
9 you is that of the 52 hospitals at the time, nine
10 of them or 17 percent did not have access to
11 echocardiograms. And the significance of that is
12 that if those hospitals happen to have a failed
13 screen, potentially they would need to transfer the
14 baby.

15 About 2 months into it, I sent out
16 another survey. This was actually right before our
17 meeting so I didn't do any follow-up, so I was
18 actually happy with a 50 percent response rate.
19 Interestingly, all the hospitals that responded
20 said that they were actually using our recommended
21 protocol. And overall, I asked them about
22 implementation was going and for the most part,

1 most said it was going fairly smoothly. I think
2 the biggest challenge that the hospitals face was
3 trying to develop a mechanism to track the babies
4 that they were screening. Some easily were able to
5 incorporate it into their EHR's, their electronic
6 health records. Others, it has been a challenge
7 for them. Some are still using paper and pencil
8 logs, which is very laborious for them.

9 I just wanted to mention back on that
10 slide, in addition, we really didn't get, or at
11 least I didn't hear that much pushback from the
12 hospitals. And most of nurses in most of the
13 hospital said it was fairly easy to incorporate and
14 just treat it as another vital sign.

15 I titled this "preliminary data." It's
16 very much preliminary and if I could have put a big
17 watermark that said "draft" across it, I would
18 have. We just got our first quarterly reports
19 within the last couple of weeks. We have it on all
20 of the hospitals, except we are missing one
21 hospital at this point.

22 So this is really changing as we have

1 back-and-forth with the hospitals as we get -- the
2 data has been changing. But I just wanted to give
3 you a sense of where we are at.

4 So basically, the first number is the
5 number of live births that we would have expected
6 to have been screened, 24,807. Of those babies,
7 24,343 were screened, so that was 98 percent. We
8 had nine failed screens and two of those were in
9 asymptomatic babies that did have critical
10 congenital heart disease.

11 So I just wanted to discuss a little bit
12 of the challenges and the strengths, and then I
13 will close.

14 So overall, I think a major challenge
15 with a 90-day implementation period, we were able
16 to get up and running within that time, but we find
17 that now we are doing a lot of the things that
18 ideally we would have done prior to implementing at
19 the statewide level. This was an unfunded mandate.
20 We were short staffed before we started, and this
21 is put a stress on the staffing that we had, and it
22 has affected the speed with which we can move

1 forward. And I just put on here inclusion of all
2 infants including the NICU babies. It is not as
3 straightforward screening in NICU babies, as was
4 mentioned in the strategies paper. And I'm happy
5 to go into that further with anybody who is
6 interested afterward.

7 As far as education, I mentioned that we
8 really do need to get out and do more intensive
9 training. And speaking to the surveillance system,
10 the accuracy of the data has been a real steep
11 learning curve for us, but I think that is to be
12 expected with any surveillance system that is
13 implemented. And we are just at the beginning of
14 it.

15 As far as the aggregate data, I think it
16 is sufficient. I think it gives us a picture of
17 what is going on, but it is complicated. We have
18 babies, especially since we're screening the NICU
19 babies, that are born in one quarter, but,
20 appropriately so, aren't screened for a couple
21 months later, until the next quarter. We have
22 transfers in, transfers out. So dealing with that

1 in aggregate data is just challenging. Once we go
2 to individual level data, that will largely be
3 eliminated.

4 In quality assurance, obviously
5 incredibly important in data collection, and
6 something that will remain a challenge for us as
7 long as the resources are what they are.

8 So our strengths, I think you know the
9 good thing is we got up and running, and we got up
10 and running fast. And in the first 90 days, we had
11 greater than 95 percent of the infants in the
12 birthing facilities that were screened. In talking
13 with the hospitals, they are aware of the gaps in
14 the missed babies, and they think that that number
15 is only going to get higher.

16 We put in place a mechanism to collect
17 data for program evaluation. It is a work in
18 progress, but we're able to get a sense of what is
19 going on out there.

20 I think we covered a lot of ground with
21 very limited resources, and it really couldn't have
22 happened without a committed working group, the

1 dedicated staff of the department, and I think also
2 the established connections that we already had
3 with the birthing facilities.

4 I close with a picture. This is baby
5 Dylan Gordon. He is the first baby that was
6 identified through the pulse ox screening program,
7 and there is just a quote that was from a letter
8 that his family had written to the governor.

9 And this is my e-mail address. If
10 anybody has any questions, I'm happy to shed light
11 on what we have done.

12 Thank you.

13 CHAIRMAN BOCCHINI: Thank you. That is a
14 wonderful presentation and shows a dramatic
15 implementation effort. That's wonderful.

16 Questions or comments?

17 Alexis?

18 DR. THOMPSON: Just for clarification, I
19 know that by any means we're going to hold you to
20 the numbers, but when you mentioned the two true
21 cases, that they were asymptomatic, during that
22 same time period, were there other cases that were

1 symptomatic that were also screened?

2 DR. GARG: Yes, so in the nine fails,
3 yes, we are actually still having conversations
4 with the hospitals. But one of the babies was
5 prenatally diagnosed, asymptomatic but prenatally
6 diagnosed, so I didn't count that in the two. I
7 was trying to get at the two cases that we wouldn't
8 have otherwise caught.

9 CHAIRMAN BOCCHINI: Coleen, and then
10 Jeff.

11 DR. BOYLE: Do you information on the
12 seven that words true cases?

13 DR. GARG: I do, but I think I'd --

14 DR. BOYLE: Would rather not share?

15 DR. GARG: I think I would have to talk
16 to the hospitals more.

17 Dr. GUTTMACHER: Your general
18 impressions?

19 DR. GARG: Of the fails?

20 Dr. GUTTMACHER: Yes.

21 DR. GARG: So two of them, the best I can
22 tell at this point, I think probably would have

1 otherwise been detected, not from -- even if we
2 hadn't been screening. There were a couple that --
3 there was one that was diagnosed with sepsis. A
4 couple that we need to look into a little further.
5 I don't know at this point that I can say, oh, they
6 had conditions that wouldn't have been -- that it
7 was still important to detect. I don't know enough
8 about them at this point.

9 CHAIRMAN BOCCHINI: Jeff?

10 Dr. Botkin: Yes, question about funding.
11 I am wondering how the hospitals are billing this
12 out, whether they have had any challenges with the
13 billing for the screening service. And then on the
14 health department side, are you considering any
15 funding model for the level of support that you are
16 providing? Or is it going to continue to be an
17 unfunded activity?

18 DR. GARG: As far as the hospitals, so,
19 it's anecdotal at this point. From what I know
20 about the hospitals, I think that the sense I'm
21 getting is that most of them have just absorbed it,
22 they are not able to bill for it, because they're

1 either bundled in their reimbursement -- so I don't
2 know that is something that when they negotiate --
3 the next time they have negotiations that they will
4 be able to include that or not.

5 We did get some concerns raised about the
6 cost, but it wasn't a huge pushback that we got.
7 Initially, with the probes and trying to find out
8 how to purchase that, it was something that we
9 heard a little bit about. But we had concerns
10 about will the transports be covered in WellCare
11 baby, but I don't have enough experience to know
12 that.

13 As far as at the department, we applied
14 for the HRSA grant. I think other than that, I
15 don't get the sense that if we go for a fee
16 increase that this would be -- that money would go
17 towards this. But our revenue is through the kits,
18 the newborn screening kits that we sell. I think
19 this is an unfunded mandate.

20 CHAIRMAN BOCCHINI: Yes?

21 Ms. LIGHT: Kelly Light. I just wanted
22 to say that, as a New Jersey resident and consumer

1 advocate, I want to commend you on putting together
2 a remarkable program with remarkable saturation and
3 coverage of the babies over a short period of time
4 with no funding. I think it is pretty incredible,
5 and I commend you for that.

6 DR. GARG: Thank you.

7 CHAIRMAN BOCCHINI: Questions, comments?

8 Again, I think the committee feels the
9 same way, so thank you very much.

10 DR. GARG: Thank you very much.

11 CHAIRMAN BOCCHINI: Thank you for coming.

12 The last implementation presentation is
13 by Mr. Bob Bowman. Mr. Bowman is the director of
14 genomics and the newborn screening program at the
15 Indiana State Department of Health. He oversees
16 the screening program in early hearing detection
17 and genetics program and --

18 Dr. Bowman: That is correct.

19 Well, things moved fairly quickly in
20 Indiana as well, not quite as quickly as they did
21 in New Jersey. But in the spring of 2011, we
22 started hearing that there was a bill that was

1 proposed to our state legislature to include
2 congenital heart defects on our newborn screening
3 and that was the proposal, that it would actually
4 be added to our newborn screening law.

5 There were other priorities for the
6 legislature that year, and it sort of just
7 disappeared for a while. We didn't hear much about
8 it. But then in June, we heard that it had been
9 added to our state law, and we were told that we
10 had to give a report to the legislature on October
11 31 and that we had to go to statewide screening as
12 of January 1, 2012.

13 So this put us in a little bit of a
14 dilemma. We had to quickly assess where we were
15 and what was going on. It also sort of spelled out
16 what our responsibilities were, by adding it to the
17 newborn screening law. What this meant, the way it
18 was incorporated, the state Department of Health,
19 specifically the newborn screening program, was
20 going to be responsible for developing a tracking
21 and surveillance component, but there's another
22 part of our law which says that we are also

1 responsible for the follow-up and the diagnostic
2 part, which that was set aside for pulse oximetry
3 screening.

4 So the first thing we did was we really
5 tried to quickly assess where we stood as a state
6 and what we needed to do. There are five things
7 that we sort of teased out that we needed to
8 address.

9 The first thing we wanted was the
10 complete recommendations from the Secretary's
11 advisory committee. Alex's paper had not yet been
12 released, so it made it a little difficult as to
13 what we could share with the different positions
14 and birthing facilities across the state. We have
15 100 birthing facilities in Indiana, give or take.
16 It seems to change on a daily basis.

17 The second thing, we wanted to determine
18 the capacity of the birthing facilities to do this
19 screen. How many of them actually have these pulse
20 oximeters, have the appropriate probes, how many of
21 them could do it? The third thing was we wanted to
22 get feedback from pediatric cardiologists in

1 Indiana.

2 When this was first brought to our
3 attention, we did a little research to determine
4 how many pediatric cardiologists there are in
5 Indiana. And we are fortunate to have an
6 integrated database, and we actually have the
7 licensing information in Indiana. So we were able
8 to find out that there were 24 pediatric
9 cardiologists in the state, and most of them were
10 associated with one of the two larger birthing or
11 hospital groups.

12 So we wanted to get in touch with them
13 and find out their take, how did they think this
14 law, this new change, how would it affect them. We
15 also wanted to determine how the birthing
16 facilities felt about implementing the screen.

17 For us, this was arguably the most
18 important thing. And the reason that is, is we
19 have seen in the past that the medical field at
20 times can view these things as it is the state
21 telling us what to do, and we didn't want them to
22 feel this way. We wanted them to feel that this is

1 a collaboration, we're in this together, we will
2 get through this. And so we really wanted to see
3 how they took it.

4 There was some misconception that people
5 did not understand or didn't recognize that the
6 Secretary's committee had made this recommendation,
7 or even that their own legislature had passed this
8 law, so there was some education to do on that
9 side.

10 The final priority was identify what data
11 would be collected and how it would be collected.

12 This is our final priority, because we
13 realized that this was going to be a difficult
14 task. It was not something that we could probably
15 fully address by January 1. We figured we could
16 have a pretty good head start and hopefully
17 establish the framework to move forward.

18 So the first thing we did was we
19 developed a list of individuals that we felt we
20 needed to contact and start developing a rapport
21 with, that included the neonatologists, the nurses,
22 the pediatric cardiologists, and the birthing

1 facilities.

2 We sent out a survey. As I mentioned
3 before, we have an integrated system in Indiana, so
4 we have access to a lot of e-mail addresses through
5 Medicaid and through the licensing board. So we
6 did surveys and e-blasts and things like that.

7 First, we just wanted to take a more
8 broad approach and determine where things stood.
9 We have things such as, does your facility already
10 perform pulse oximetry screening? Can you perform
11 it? Do you have the capacity? Do you have people
12 who are trained to do this?

13 And we heard back from about half of the
14 birthing facilities and what we heard in general
15 was that, yes, most of them did have the capacity
16 to actually do pulse oximetry screenings. So we
17 thought that was a very good thing and something
18 that we felt we could move forward with.

19 The other significant thing was that we
20 found that about 60 percent, 58 percent, that did
21 report back to us so said that they could do the
22 echo at their own facility as well, which meant

1 that these children would not need to be referred
2 to another facility. So this was significant as
3 well.

4 We discussed how exactly this would
5 happen, because we knew there were only 24
6 pediatric cardiologists in the state, and what we
7 heard was that a lot of them have the technicians
8 who can do the pediatric echo and then the results
9 would be transmitted electronically to a pediatric
10 cardiologist who they are working with, who
11 actually would interpret those results.

12 So that made us feel a little better as
13 well. And you can see down below. We started
14 teasing out some of the specifics. Riley Hospital
15 for Children is part of the I.U. health system
16 network and St. Vincent Hospital is part of the
17 Ascension health network, and those are the two
18 largest networks in our state.

19 After talking to Indiana physicians and
20 after actually getting the protocols from Alex's
21 paper, we provided the physicians with that
22 information. They reviewed the protocols. In

1 general they didn't see any problem with
2 implementing them statewide.

3 We still had a lot of questions.
4 Specifically, about NICU children, about premature
5 children, things like that. How would the screens
6 be done?

7 Through this whole process, I had a
8 number of discussions with our legal staff about
9 what we could do and what we couldn't do.

10 It was at this point that I was advised
11 that we could not make additional recommendations
12 about those children. Basically, all that we could
13 say was that it was up to each birthing facility to
14 develop their own protocols for NICU children and
15 premature children. So that's basically what we
16 had to tell the different birthing facilities.

17 That was not an easy thing for me to do,
18 and it was not easy thing for them to hear.

19 Also, we heard back a little bit from the
20 pediatric cardiologists. We didn't communicate
21 with them directly. We were working through the
22 neonatologists who were meeting with the pediatric

1 cardiologists. But the main things that we heard
2 from them was that they had some concerns about
3 once this goes statewide, what are we going to see
4 in the way of false positives. Because we do have
5 hundred birthing facilities, there are some smaller
6 birthing facilities. What it was the number of
7 false positives going to look like, and how
8 inundated are they going to become? That is
9 something that we don't have an answer for at this
10 particular point in time, because we just started
11 January 1.

12 The other real question that they had was
13 the transportation issue. Forty percent of the
14 children would need to be transferred to another
15 facility, and recommendations are "in a timely
16 manner," so there is some question, what exactly
17 does that mean? Do we have to life flight the
18 children? Do we have to transport them by
19 ambulance? Can we tell the parents they can take
20 them in the car quickly to have an echo done?
21 Again, I was left with having to tell them it was
22 something that, an individual basis, they had to

1 determine their own protocols.

2 So, by October, we had gotten feedback,
3 protocols and we sent out our second e-blast to all
4 these individuals who are listed here. And we
5 included what the protocols were, what the
6 finalized protocols were, an update letter from us,
7 a link to our website. We developed a frequently
8 asked questions sheet that sort of took them
9 through a number of the different questions that we
10 were getting hit with. And we also told them that
11 they would be required to submit to us on a monthly
12 basis. So this was the part where we started
13 addressing the data.

14 We have an integrated data system where
15 we're linking to birth certificates, newborn
16 screening results, hearing screening results. And
17 our latest application, which we refer to as
18 instep, that is for the Indiana Newborn Screening
19 and Tracking an Education Program. It is really a
20 third-generation application. And the way we
21 constructed it is basically it is modulized, so it
22 didn't take our programmers a whole lot of time to

1 develop a new module for congenital heart defects.

2 The key issue was what specifically were
3 we going to be asking the hospitals to report to
4 us? Based on our conversations with the birthing
5 facilities, we decided to go very similar to what
6 we were doing with other monthly reports for
7 newborn screening and for hearing screening, and
8 that was we would like to know those children who
9 do not pass. If they did not pass, we would like
10 to know where they were referred to. We would like
11 to know those children who were transferred to
12 another facility where they received the pulse
13 oximetry screen. And we would like to know those
14 children who did not receive a pulse oximetry
15 screening and why they did not receive it. Because
16 one of the things that we recognized is it would be
17 legally possible for a parent to refuse pulse
18 oximetry screening based on religious reasons,
19 which also meant we had to change the religious
20 waiver.

21 So we developed the second survey at that
22 time, and we asked very quick questions. We really

1 wanted to ascertain at this point whether everybody
2 had been alerted to the fact that pulse oximetry
3 screening, CCHD screening, would go statewide
4 January 1 and to make sure that they had some sort
5 of protocols in place as to whether or not they
6 were going to refer this children to.

7 So that's what this survey was really
8 trying to determine. What facility do you come
9 from? And where are you going to be referring
10 these children to?

11 And we heard back from, initially, 94
12 birthing facilities. That was as of 12/27. I
13 think we got up to 97, but then we found out that
14 there were few birthing facilities that had closed,
15 a few we're still working on, contacts who had
16 left, things like that. But for the most part, we
17 heard back from all the different birthing
18 facilities.

19 What we saw was a slight change in some
20 of the numbers. We saw 46.8, so almost 47 percent,
21 of the ECHOs would actually be performed in the
22 same facility, slightly lower than what we had

1 heard before, but we did get that information and
2 we were able to confirm that the different
3 facilities were aware of it, and they did have
4 protocols in place to move forward.

5 So based on the feedback we got, as I
6 mentioned before, we had updated the religious
7 waiver form. We updated the professionals website,
8 gave them a little bit more information. And we
9 created a parent education sheet.

10 And here it is. This is just part of our
11 webpage. It seems to get longer every day now.
12 This is actually the education sheet. And this is
13 something that we reviewed internally. We had
14 physicians look at it. We also sent it to a mother
15 of an Indiana child whose daughter had one of the
16 heart defects, and she reviewed it and she gave us
17 her input on it as well, and we were able to make
18 some adjustments to it as well.

19 The monthly summary report, I think I
20 have already talked about this. Like I said, our
21 programmers were able to move fairly quickly on
22 this. We had this up and tested in about 6 weeks.

1 So where we are right now with this is
2 every birthing facility has an individual who can
3 log into our web-based application and enter
4 information for heel stick screening and for
5 hearing screening. This is another module like
6 that.

7 We have a problem now. And that is that
8 some of the birthing centers have designated
9 another individual to enter the information. So we
10 also had to do a paper form and distribute that to
11 the birthing centers, so that they could enter the
12 same information on paper, fax it to us, and we
13 would have to have staff enter the information into
14 our own system until we can get all the facilities
15 trained. Right now, it is about 50-50.

16 In terms of long term, where do we want
17 to go with this? We discussed this is good and
18 this is the way newborn screening had worked in the
19 past, but our ultimate goal is to have all the
20 screening information for each one of these
21 children, because we want to make it readily
22 available to pediatricians when the child is in

1 their office.

2 And we had discussions about if we don't
3 have any information, can we say that that means
4 that that child passed. None of us feel
5 comfortable with that. We feel that we need the
6 information.

7 So how do we get that information? There
8 are two ways that we've looked at. Currently, with
9 what we're doing with hearing screening, we are
10 getting that information on the blood spot card.

11 We have talked about what that would mean
12 if we added congenital heart disease to the blood
13 spot card as well. We're looking at about an 8x11
14 card at this point. It is still being considered.

15 The other thing that we have discussed is
16 contracting with an outside vendor and getting the
17 results directly from the screening equipment. And
18 that is something that it seems very feasible, and
19 we are actually in the process of contract
20 negotiations with that right now. We are hoping
21 this is the way we can go. It's still a little up
22 in the air at this point.

1 So a little bit more about the monthly
2 with summary report. I think I already have gone
3 through this, with the did not pass or they did not
4 receive a valid screen. That was another exception
5 code that they birthing centers will be -- to it.

6 The long-term information, as I
7 mentioned, the pulse oximetry screening or CCHD
8 screening had gotten added to the newborn screening
9 law, there was no diagnosis, no follow-up part
10 attached to it, so this was completely separate.
11 This put us in a little bit of a dilemma and the
12 pediatricians, neonatologists and the pediatric
13 cardiologists agreed that that was not sufficient.
14 We needed to know outcomes for these different
15 newborns as to what happened, so how were we going
16 to do that?

17 There was talk about linking it to the
18 birth defects and problems registry, as these are
19 on the birth defects and problems registry, but it
20 means drastic revisions to the birth defects and
21 problems registry. As I mentioned previously, our
22 INSTEP application is our third generation. Our

1 birth defects and problems registry was our very
2 first web-based application.

3 Our birth defects and problems registry
4 functions by getting billing codes from hospitals
5 on children up to the age of 3. We have a hybrid
6 system where we have we -- we go to the individual
7 hospitals -- I'll remind you there are hundred
8 birthing centers throughout the State of Indiana --
9 and look as these children's medical records.
10 Children are reportable to the birth defects and
11 problems registry up to the age of 3. And it is
12 about 3 years later that we are doing audits on
13 these children. That is insufficient for CCHD. So
14 that means some major changes need to be made to
15 the birth defects and problems registry so we can
16 act a little quicker on some of the things that
17 we're considering right now.

18 We also had to have some discussions with
19 our legal staff about whether if we have a child
20 who did not pass their pulse oximetry screening,
21 and we knew where they were referred, could we turn
22 that child over to the birth defects and problems

1 registry and go audit their chart.

2 I was a little concerned about what they
3 would say, but they said, yes, that is something we
4 can do to confirm the child did not have heart
5 disease.

6 So this is how we plan on utilizing the
7 information in the birth defects and problems
8 registry, to ensure that those children who did not
9 pass the screen receive follow-up care, evaluate
10 the health-related outcomes for those children, and
11 evaluate and potentially modify the current
12 standards of care for Indiana children with CCHDs.

13 So where do we stand right now in
14 Indiana? What is still hanging out there? Well, I
15 already mentioned that probably the number one
16 thing is the lack of protocols for NICU or
17 premature or unhealthy newborns. This second thing
18 is the lack of recommendations for newborns
19 discharged prior to 24 hours.

20 When I was first asked about that, I
21 thought well, we could do the same thing that we do
22 with the hearing screen or the blood spot

1 screening. It became obvious to me after some
2 discussions with some of the nurses that that was
3 not the case. This is different. It just won't
4 fit to have the exact same protocols.

5 So in terms of recommendations for having
6 those children come back or go to a facility, if it
7 is the case of the homebirth, in what timeframe
8 does that need to occur? That is something that
9 needs to be addressed.

10 Lack of recommendations for asymptomatic
11 newborns who needed to be transported for an echo
12 is another thing that needs to be addressed.

13 And finally, I tried to think of just how
14 many of the birthing centers asked me about which
15 pulse oximeters, which probes were acceptable,
16 because they wanted an actual list, and I was
17 unable to provide them with that. And I haven't
18 been able to find one. So if there's anybody in
19 the room right now who happens to know of such a
20 list, please tell me, because I would really
21 appreciate finding out about that.

22 Some other questions, will there be any

1 accreditation for referral sites? We were talking
2 about this with respect to what we do with cystic
3 fibrosis. There are different centers that are CF
4 accredited. And we can say with confidence, these
5 are the facilities they should go to.

6 Right now the recommendation is children
7 should have a pediatric ECHO that is reviewed by a
8 pediatric cardiologist. Are all those the same?
9 What I was hearing is that there is some
10 difference, so it's just something that has been
11 asked.

12 How will the program be evaluated? What
13 data should be collected, specifically on cost
14 analysis, and how should that be collected?
15 Because that is proving a little difficult, too.

16 Fortunately, I feel like we do have a
17 pretty good relationship with some of the
18 hospitals, and they have offered to provide us with
19 some of this information. And they would just like
20 to know what we are going to be asking for.

21 Once the FDA makes its recommendations
22 for pulse oximeters, will funding be made available

1 to birthing centers to meet these recommendations?
2 Because again, we have some smaller birthing
3 centers in the state of Indiana who, this is a
4 concern, how they will cover the cost of buying
5 these.

6 And finally, what CBT codes will be
7 developed for this? We've heard the same thing,
8 where there are problems with billing for
9 screening. Some have been able to roll it into the
10 overall newborn screening costs, but there have
11 been problems with that as well.

12 Future activities, this is something that
13 we said pretty much from the start: pulse oximetry
14 in the State of Indiana will be a work in progress.
15 It will be a work in progress for a while.

16 We plan on implementing more data
17 collection as we move forward. Hopefully we go
18 down the path of the electronic transmission of
19 that data from the oximeters.

20 We will make sure that we train the
21 individuals who will be entering the information on
22 the monthly summary reports to us, so that

1 hopefully by June or July of 2012, all of the
2 facilities will be reporting to us electronically
3 instead of by paper, or half of them by paper.

4 And we hope to develop additional parent
5 educational material as we move forward.

6 So any questions? I feel like I have
7 gotten these looks quite a bit over the past few
8 months.

9 [Laughter.]

10 CHAIRMAN BOCCHINI: Thank you. Thank
11 you, Bob, for a nice presentation and another good
12 example of a real serious effort, and some of the
13 barriers and hurdles you need to go through to
14 implement this. So I think this is very telling to
15 the committee and very important for us as we
16 understand that implications of what we do and the
17 recommendations that we make.

18 Comments? Questions?

19 Was there any interaction between you and
20 other states that are doing this? Could you sort
21 of talk to them about the same things that they
22 were going through?

1 Dr. BOWMAN: I actually regret I did not
2 get in touch with New Jersey. I did hear from a
3 number of states who were calling me, asking me
4 what we were doing. But that was the level of it.

5 With the way it was added to our law, I
6 think it was a little different too, and that made
7 it a little unique.

8 CHAIRMAN BOCCHINI: Okay, thank you.

9 Any questions or comments?

10 If not, thank you again for the
11 presentation.

12 Are there any other issues for the
13 committee? I think the only thing that I want to
14 mention is that the Wisconsin group that brought
15 the nomination for the 22q11 Deletion Syndrome will
16 provide us additional data on distribution of the
17 severe immune deficiency and critical congenital
18 heart lesions in the wider spectrum of patients
19 with the disorder. We have not received that yet,
20 but when we do, we will go ahead and post that
21 along with the other information concerning the
22 meeting.

1 Any other issues that need to come
2 forward?

3 Sara?

4 DR. COPELAND: Nope. See you in May.

5 CHAIRMAN BOCCHINI: Okay, if not, thank
6 you very much.

7 Thank you for all your contributions to
8 the meeting.

9 [Whereupon, at 2:40 p.m., the meeting was
10 adjourned.]

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